

Equivalent of Form PTO/SB/08B (10-07)
Approved for use through 10/31/2007. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Project of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

THIRD SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)		Complete if Known			
		Application Number	10/725,015		
		Filing Date	December 2, 2003		
		First Named Inventor	GEALL, Andrew		
		Art Unit	1635		
		Examiner Name	SCHNIZER, Richard A.		
Sheet	1	of	4	Attorney Docket Number	1530.0610001/EJH/UWJ

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T ²
BS	NPL1	BAUMGARTNER, I., <i>et al.</i> , "Constitutive Expression of phVEGF ₁₆₅ After Intramuscular Gene Transfer Promotes Collateral Vessel Development in Patients With Critical Limb Ischemia," <i>Circulation</i> 97:1114-1123, American Heart Association, Inc. (1998)	
	NPL2	CHEN, Z.Y., <i>et al.</i> , "Linear DNAs Concatemerize <i>in Vivo</i> and Result in Sustained Transgene Expression in Mouse Liver," <i>Mol. Ther.</i> 3:403-410, The American Society of Gene Therapy (2001)	
	NPL3	CHENG, S.H., and SCHEULE, R.K., "Airway delivery of cationic lipid: DNA complexes for cystic fibrosis," <i>Adv. Drug Deliv. Rev.</i> 30:173-184, Elsevier Science B.V. (1998)	
	NPL4	CHERNG, J.-Y., <i>et al.</i> , "Effect of DNA topology on the transfection efficiency of poly((2-dimethylamino)ethyl methacrylate)-plasmid complexes," <i>J. Control. Release</i> 60:343-353, Elsevier Science B.V. (1999)	
	NPL5	CHERNG, J.-Y., <i>et al.</i> , "Stabilization of polymer-based gene delivery systems," <i>Intl. J. Pharm.</i> 183:25-28, Elsevier Science B.V. (1999)	
	NPL6	CORVELEYN, S, and REMON, J.P., "Maltodextrins as Lyoprotectants in the Lyophilization of a Model Protein, LDH," <i>Pharm. Res.</i> 13:146-150, Plenum Publishing Corporation (1996)	
	NPL7	DALESANDRO, J., <i>et al.</i> , "Gene Therapy for Donor Hearts: Ex Vivo Liposome-Mediated Transfection," <i>J. Thorac. Cardiovasc. Surg.</i> 111:416-422, Mosby-Year Book, Inc. (1996)	
	NPL8	DANKO, I., <i>et al.</i> , "Dystrophin expression improves myofiber survival in <i>mdx</i> muscle following intramuscular plasmid DNA injection," <i>Hum. Mol. Genet.</i> 2:2055-2061, Oxford University Press (1993)	
	NPL9	DARQUET, A.-M., <i>et al.</i> , "A new DNA vehicle for nonviral gene delivery: supercoiled minicircle," <i>Gene Ther.</i> 4:1341-1349, Stockton Press (1997)	
	NPL10	DAVIS, H.,L., <i>et al.</i> , "Direct gene transfer in skeletal muscle: plasmid DNA-based immunization against the hepatitis B virus surface antigen," <i>Vaccine</i> 12:1503-1509, L.R. Printing Services Ltd. (1994)	

Examiner Signature	Date Considered
--------------------	-----------------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 809. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.
This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

THIRD SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>		Complete if Known			
		Application Number	10/725,015		
		Filing Date	December 2, 2003		
		First Named Inventor	GEALL, Andrew		
		Art Unit	1635		
		Examiner Name	SCHNIZER, Richard A.		
Sheet	2	of	4	Attorney Docket Number	1530.0610001/EJH/UWJ

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume number, publisher, city and/or country where published	T ²
	NPL11	DOW, S.W., <i>et al.</i> , "Systemic and Local Interferon γ Gene Delivery to the Lungs for Treatment of Allergen-Induced Airway Hyperresponsiveness in Mice," <i>Hum. Gene Ther.</i> 10:1905-1914, Mary Ann Liebert, Inc. (1999)	
	NPL12	GRAMZINSKI, R., <i>et al.</i> , "Immune Response to a Hepatitis B DNA Vaccine in Aotus Monkeys: A Comparison of Vaccine Formulation, Route, and Method of Administration," <i>Mol. Med.</i> 4:109-118, The Picower Institute Press (1998)	
	NPL13	HARLAND, R., and MISHER, L., "Stability of RNA in developing <i>Xenopus</i> embryos and identification of a destabilizing sequence in TFIIA messenger RNA," <i>Development</i> 102:837-852, The Company of Biologists Limited (1988)	
	NPL14	HORTON, H.M., <i>et al.</i> , "A gene therapy for cancer using intramuscular injection of plasmid DNA encoding interferon α ," <i>Proc. Natl. Acad. Sci. USA</i> 96:1553-1558, National Academy of Sciences (1999)	
	NPL15	KIM, A.I., <i>et al.</i> , "The Physical State of Mannitol after Freeze-Drying: Effects of Mannitol Concentration, Freezing Rate, and a Noncrystallizing Cosolute," <i>J. Pharm. Sci.</i> 87:931-935, American Chemical Society (1998)	
	NPL16	LEVY, M.Y., <i>et al.</i> , "Characterization of plasmid DNA transfer into mouse skeletal muscle: evaluation of uptake mechanism, expression and secretion of gene products into blood," <i>Gene Ther.</i> 3:201-211, Stockton Press (1996)	
	NPL17	MARTINI, A., <i>et al.</i> , "Use of subambient differential scanning calorimetry to monitor the frozen-state behavior of blends of excipients for freeze-drying," <i>PDA J. Pharm. Sci. Tech.</i> 51:62-67, PDA, Inc. (1997)	
	NPL18	MARTINI, A., <i>et al.</i> , "Use of subambient differential scanning calorimetry to monitor the frozen state behaviour of amino acids in simulated freeze-drying conditions," <i>STP Pharma. Sci.</i> 7:377-381, STP Pharma Sciences (1997)	
	NPL19	MIR, L.M., <i>et al.</i> , "High-efficiency gene transfer into skeletal muscle mediated by electric pulses," <i>Proc. Natl. Acad. Sci. USA</i> 96:4262-4267, National Academy of Sciences (1999)	
	NPL20	MOFFATT, M., and COOKSON, W., "Naked DNA: New shots for allergy?," <i>Nat. Med.</i> 2:515-516, Nature America Inc. (1996)	

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

THIRD SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)		Complete if Known			
		Application Number	10/725,015		
		Filing Date	December 2, 2003		
		First Named Inventor	GEALL, Andrew		
		Art Unit	1635		
		Examiner Name	SCHNIZER, Richard A.		
Sheet	3	of	4	Attorney Docket Number	1530.0610001/EJH/UWJ

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume number, publisher, city and/or country where published	T ²
	NPL21	MOLINA, M.C. <i>et al.</i> , "Maintenance of nonviral vector particle size during the freezing step of the lyophilization process is insufficient for preservation of activity: insight from other structural indicators." <i>J. Pharma. Sci.</i> 90:1445-1455, Wiley-Liss, Inc (October 2001)	
	NPL22	NOVO, F.J., <i>et al.</i> , "Gene transfer and expression of human α -galactosidase from mouse muscle in vitro and in vivo," <i>Gene Ther.</i> 4:488-492, Stockton Press (1997)	
	NPL23	OLIYAI, C., <i>et al.</i> , "Chemical Pathways of Peptide Degradation. VII. Solid State Chemical Instability of an Aspartyl Residue in a Model Hexapeptide," <i>Pharma. Res.</i> 11:901-908, Plenum Publishing Corporation (1994)	
	NPL24	ORIZIO, G., <i>et al.</i> , "Freeze-dried mannitol for injectable preparations using an automatic lyophilization cycle," <i>Boll. Chim. Farmaceutico</i> 132:368-374, Società Editoriale Farmaceutica (1993)	
	NPL25	ÖSTERBERG, T., <i>et al.</i> , "Development of a Freeze-Dried Albumin-Free Formulation of Recombinant Factor VIII SQ," <i>Pharma. Res.</i> 14:892-898, Plenum Publishing Corporation (1997)	
	NPL26	PELLETIER, J., and SONENBERG, N., "Internal initiation of translation of eukaryotic mRNA directed by a sequence derived from poliovirus RNA," <i>Nature</i> 334:320-325, Macmillan Magazines Ltd. (1988)	
	NPL27	PICCIRILLO, C.A., and PRUD'HOMME, G.J., "Prevention of Experimental Allergic Encephalomyelitis by Intramuscular Gene Transfer with Cytokine-Encoding Plasmid Vectors," <i>Hum. Gene Ther.</i> 10:1915-1922, Mary Ann Liebert, Inc. (1999)	
	NPL28	PICCIRILLO, C.A., <i>et al.</i> , "TGF- β 1 Somatic Gene Therapy Prevents Autoimmune Disease in Nonobese Diabetic Mice," <i>J. Immunol.</i> 161:3950-3956, The American Association of Immunologists (1998)	
	NPL29	QIN, L., <i>et al.</i> , "Gene Transfer for Transplantation - Prolongation of Allograft Survival with Transforming Growth Factor- β 1," <i>Ann. Surg.</i> 220:508-519, J.B. Lippincott Company (1994)	
✓	NPL30	QIN, Y.-J., <i>et al.</i> , "Gene Suture - A Novel Method for Intramuscular Gene Transfer and its Application in Hypertension Therapy," <i>Life Sci.</i> 65:2193-2203, Elsevier Science Inc. (1999)	

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.
This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.


If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO		Complete if Known			
THIRD SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)		Application Number	10/725,015		
		Filing Date	December 2, 2003		
		First Named Inventor	GEALL, Andrew		
		Art Unit	1635		
		Examiner Name	SCHNIZER, Richard A.		
Sheet	4	of	4	Attorney Docket Number	1530.0610001/EJH/UWJ

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume number, publisher, city and/or country where published	T ²
	NPL31	RAGNO, S., <i>et al.</i> , "Protection of Rats from Adjuvant Arthritis by Immunization with Naked DNA Encoding for Mycobacterial Heat Shock Protein 65," <i>Arthritis Rheum.</i> 40:277-283, American College of Rheumatology (1997)	
	NPL32	RESTIFO, N.P., <i>et al.</i> , "Enhancing the Recognition of Tumour Associated Antigens," <i>Folia Biologica</i> 40:74-88, Institute of Molecular Genetics (1994)	
	NPL33	SCHRIJVER, R.S., <i>et al.</i> , "Immunization of cattle with a BHV1 vector vaccine or a DNA vaccine both coding for the G protein of BRSV," <i>Vaccine</i> 15:1908-1916, Elsevier Science Ltd. (1997)	
	NPL34	TRIPATHY, S.K., <i>et al.</i> , "Long-term expression of erythropoietin in the systemic circulation of mice after intramuscular injection of a plasmid DNA vector," <i>Proc. Natl. Acad. Sci. USA</i> 93:10876-10880, National Academy of Sciences (1996)	
	NPL35	TSURUMI, Y., <i>et al.</i> , "Direct Intramuscular Gene Transfer of Naked DNA Encoding Vascular Endothelial Growth Factor Augments Collateral Development and Tissue Perfusion," <i>Circulation</i> 94:3281-3290, American Heart Association, Inc. (1996)	
	NPL36	ULMER, J.B., <i>et al.</i> , "Immunization against Viral Proteins with Naked DNA," <i>Ann. N.Y. Acad. Sci.</i> 772:117-125, New York Academy of Sciences (1995)	
	NPL37	VAHLSING, H.L., <i>et al.</i> , "Immunization with plasmid DNA using a pneumatic gun," <i>J. Immunol. Methods</i> 175:11-22, Elsevier Science B.V. (1994)	
	NPL38	YAGI, K., <i>et al.</i> , "Basic Study on Gene Therapy of Human Malignant Glioma by Use of the Cationic Multilamellar Liposome-Entrapped Human Interferon β Gene," <i>Hum. Gene Ther.</i> 10:1975-1982, Mary Ann Liebert, Inc. (1999)	

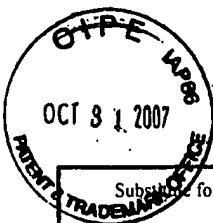
742028v1

Examiner Signature		Date Considered	1/1/08
--------------------	---	-----------------	--------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.
 This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.



Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Equivalent of Form PTO/SB/08A (10-07)
Approved for use through 10/31/2007. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Substitute for form 1449/PTO		Complete if Known	
THIRD SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)		Application Number	10/725,015
		Filing Date	December 2, 2003
		First Named Inventor	GEALL, Andrew
		Art Unit	1635
		Examiner Name	SCHNIZER, Richard A.
Sheet	1 of 1	Attorney Docket Number	1530.0610001/EJH/UWJ

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			
VJ	US1	5,641,665	06/24/1997	Hobart <i>et al.</i>	
	US2	5,679,354	10/21/1997	Morein <i>et al.</i>	
	US3	5,703,055	12/30/1997	Felgner <i>et al.</i>	
	US4	5,811,088	09/22/1998	Hunter <i>et al.</i>	
	US5	5,817,334	10/06/1998	Schmidt <i>et al.</i>	
	US6	5,824,322	10/20/1998	Balasubramanian	
	US7	6,482,518	11/19/2002	Short <i>et al.</i>	
	US8	6,875,748	04/05/2005	Manthorpe <i>et al.</i>	
	US9	7,105,574	09/12/2006	Wheeler	
	US10	7,250,404	07/31/2007	Felgner <i>et al.</i>	
	US11	2004/0162256 A1	08/19/2004	Geall <i>et al.</i>	
	US12	2005/0065107 A1	03/24/2005	Hobart <i>et al.</i>	
	US13	2006/0024670 A1	02/02/2006	Luke <i>et al.</i>	
	US14	2006/0134221 A1	06/22/2006	Geall, A.	
	US15	2007/0105193 A1	05/10/2007	Vilalta <i>et al.</i>	
	US16	2007/0105799 A1	05/10/2007	Hermanson, G.G.	

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Country Code ³ Number ⁴ Kind Code ⁵ (if known)				
VJ	FPI	WO 2001/065911 A2	09/13/2001	Valentis, Inc.		

742054v1

Examiner Signature		Date Considered	1/24/07
--------------------	--	-----------------	---------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.